

U.S. Serial No.: 09/305,738Docket No.: 2324-7028US1REMARKSStatus Of Claims

Applicants respectfully request entry of this Amendment and reconsideration of this application.

Applicants acknowledge the Examiner's conclusion that claims 27-33, 36, 72-78 and 88-90 are drawn to allowable subject matter.

Allowable claim 88 is amended herein and the scope of the recitation "drug molecule" of claim 88 is now comprised in new claim 105. Allowable claims 89 and 90 have been amended for improved antecedent basis.

Upon entry of this amendment, claims 27-33, 36, 54-56, 58, 59, 65, 66, 68, 72-79, 85, 86, 88-90 and 92-114, will be pending in this application. Claims 1-26, 34, 35, 37-53, 57, 60-64, 67, 69-71, 80-84, 87 and 91 are canceled. Claims 1-26 and 35, 39-45 were canceled previously. Claims 54-56, 58, 65, 66, 68, 85 and 88-90 are amended. Claims 92-114 are newly added. No new matter is added.

Rejection For Obviousness-Type Double Patenting & Terminal Disclaimer

Claims 27-34, 36-38 and 46-90 are rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 5,959,050.

Applicants will file a supplemental paper in this regard.

Rejections Under 35 U.S.C. § 112, ¶ 2

Claims 54, 56, 58-71 and 79-86 stand rejected under 35 U.S.C. § 112, ¶ 1, as allegedly lacking support in the written description. Applicants respectfully traverse as set forth below.

U.S. Serial No.: 09/305,738Docket No.: 2324-7028US1Claim 54

Claim 54 stands rejected as allegedly lacking support for the recitation "metal".

In order to advance the prosecution of this application claim 54 is canceled herein and claim 55 has been amended to recite "gold".

However, Applicants respectfully traverse the rejection as set forth in the office action. Applicants respectfully assert that the recitation "a metal" finds support in original claim 20 which recites "the label is chosen from ... gold" which supports "a metal". A metal also finds support on page 5, line 10, which recites "Suitable labels for use ... are ... gold." One of ordinary skill in the art would know that radio-labels (page 7, lines 1-7) would include a variety of metals.

Claim 56

Claim 56 stands rejected as allegedly lacking support for the recitation "electrochemiluminescent compound".

Applicants respectfully traverse. Claim 56 recites "said label comprises at least an electrochemiluminescent compound". Support for this recitation is found at least in original claim 20 which recites "the label is chosen from ... electrochemiluminescent compounds ..."

Claim 58

Claim 58 stands rejected as allegedly lacking support for the recitation "therapy".

Applicants respectfully traverse. The utilization of the claimed invention as "a method of therapy" is supported throughout the specification. Applicants' claim to a method of "therapy" is at least supported by the disclosure cited herein. For example, page 1, lines 1-9,

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recite "The present invention concerns artificial antibodies ... as well as a method of therapy ..."

The disclosure recites:

The invention also provides fo[r] a method of therapy or diagnosis, in which artificial antibodies are administrated to a mammal body, which artificial antibodies consist of a biocompatible polymer carrying specific binding sites mimicking the properties of antibodies towards an organic molecule. (page 4, lines 1-6).

The disclosure also states "Another advantage with the fine particles is that they are more suitable for use in therapy or diagnostics." (page 4, lines 35-36).

Further, the specification discloses:

The method of therapy ... comprises several different modes of action. ... it can be used to withdraw an undesired organic molecule from a mammal body ... In another embodiment the artificial antibodies assemble around a cancer cell to indicate the presence of such a cell. In a further embodiment the artificial antibodies are bringing a drug to specific targets, for instance cancer cells. (page 5, lines 13-20).

Original claim 24 specifically recites "A method of therapy".

In order to advance prosecution, Applicants have amended claim 58 to further recite:

... a crosslinked polymer prepared by molecular imprint polymerization and having a binding site having with specificity for a target an imprinted molecule, wherein said artificial antibody has a particle size of less than about five microns,

binding a drug molecule to said artificial antibody; and

administering said artificial antibody to a mammal body, in which  
said artificial antibody carries said drug molecule to said target.

### Claim 68

Claim 68 stands rejected to as allegedly lacking support for the recitation "assembling a plurality of said artificial antibody around a cancer cell".

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Applicants respectfully traverse. Claim 68 recites "assembling a plurality of said artificial antibody around a cancer cell." This recitation is supported in the specification at least by disclosing "In another embodiment the artificial antibodies assemble around a cancer cell ..." (page 5, lines 16-18) and "... artificial antibodies are bringing a drug to ... cancer cells." (page 5, lines 18-20).

Claim 71

Claim 71 is canceled in order to advance the prosecution of this application. However, Applicants respectfully traverse the rejection of claim 71, now rendered moot, under 35 U.S.C. § 112, ¶ 1 as set forth in the Office Action.

Claim 71 recites "A method of diagnosis". This recitation finds support throughout the specification, e.g., Applicants disclose "The invention also provides for a method of ... diagnosis ...". (page 4, lines 1-6). In another example, the specification discloses:

The method of ... diagnosis according to the invention comprises several different modes of action. For example, it can be used to withdraw an undesired organic molecule from a mammal body, such as a toxin. In another embodiment the artificial antibodies assemble around a cancer cell to indicate the presence of such a cell. (page 5, lines 13-18).

Original claim 24 also recites "A method of ... diagnosis".

Claim 79

Claim 79 stands rejected as allegedly lacking support for the recitation "opiate". Applicants respectfully traverse. Claim 79 recites "The artificial antibody ... specific for an opiate molecule." This recitation finds support in the specification on page 10,

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lines 24-30, which recites "recognition in aqueous systems using other compounds such as opiates".

Claim 80

Claim 80 was rejected under 35 U.S.C. § 112, ¶ I.

Claim 80 is canceled in order to advance the prosecution of this application rendering this rejection moot. However, Applicants respectfully traverse the substance of that rejection. Claim 80 recites "A method of analyzing a fluid sample". This recitation is supported throughout the specification. For example, on page 3, lines 18-19 "The invention also provides for a method for determination of an organic molecule in a fluid sample." Further, page 3, lines 28-29, recites "There is also provided a method for separation or isolation of an organic molecule from a fluid sample". Additionally, utilizing the present invention for "detection in body fluids" is disclosed on page 5, line 35. Original claim 19 recites "A method for determination of an organic molecule in a fluid sample".

Claim 85

Claim 85 stands rejected under 35 U.S.C. § 112, ¶ 1 as allegedly lacking support for the recitation "method of purification".

Applicants respectfully traverse. Claim 85 recites "A method of purification". Support is found in Applicants' specification on page 1, line 11, reciting "Antibodies are used in ... purification". As discussed above, the specification recites the invention "can be used to withdraw an undesired organic molecule from a mammal body, such as a toxin". (page 5, lines

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13-16). Additionally, the specification discloses "There is also provided a method for separation or isolation of an organic molecule from a fluid sample" (page 3, lines 29-30).

In view of the above, each of rejected claims 54, 56, 58-71 and 79-86 is properly supported in the specification. As stated above, claims 54, 71 and 80 are canceled herein rendering their respective rejections moot. Thus, Applicants respectfully request the withdrawal of all rejections under 35 U.S.C. § 112, ¶ 1.

**Rejections Under 35 U.S.C. § 112, ¶ 1**

Claims 34, 37, 38, 46-71 and 80-86 stand rejected under 35 U.S.C. § 112, ¶ 2, as indefinite. As indicated above, claims 34, 37, 38, 46, 53, 57, 60-64, 67-71 and 80-84 are canceled rendering the respective rejections of these claims moot.

**Claim 58**

Claim 58 stands rejected under 35 U.S.C. § 112, ¶ 2 as allegedly unclear in its recitation of "therapy". Applicants respectfully traverse as one having ordinary skill in the art would understand the type of therapeutic effect in the recited context.

However, in order to advance the prosecution of this application, claim 58 is herein amended to recite

... an artificial antibody comprising a crosslinked polymer prepared by molecular imprint polymerization and having a binding site having with specificity for a target an imprinted molecule, wherein said artificial antibody has a particle size of less than about five microns;

binding a drug molecule to said artificial antibody; and

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administering said artificial antibody to a mammal body, in which  
said artificial antibody carries said drug molecule to said target.

As such, Applicants respectfully assert that claim 58 is definite and request withdrawal of its rejection under 35 U.S.C. § 112, ¶ 2.

#### Claim 66

The Examiner alleges that claim 66 recites an effect. Applicants respectfully traverse that a "therapeutic effect" is definite and this term would be clear to one of ordinary skill in the art.

However, Applicants have amended claim 66 to recite "said drug molecule therapeutically affecting said having a therapeutic effect on said target by the interaction of said drug molecule with said target."

#### Claims 85 and 86

Claims 85 and 86 stand rejected under 35 U.S.C. § 112, ¶ 2 regarding the method of purification. Applicants respectfully traverse as one having ordinary skill in the art would understand the method of purification in the recited context.

However, in order to advance the prosecution of this application, claim 85 has been amended to recite:

binding said imprinted molecule to said artificial antibody to form a bound imprinted molecule,  
removing said bound imprinted molecule from said bodily fluid,  
thereby producing a purified bodily fluid.

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As such, Applicants respectfully assert that claim 85 is definite. Further, applicants respectfully assert that dependent claim 86 is also definite.

In view of the above, Applicants request the withdrawal of the rejection of claims 85 and 86 under 35 U.S.C. § 112, ¶ 2. Further, Applicants respectfully assert that each of pending claims 34, 37, 38, 46-71 and 80-86 are definite and request the removal of all rejections and objections under 35 U.S.C. § 112, ¶ 2.

### CONCLUSION

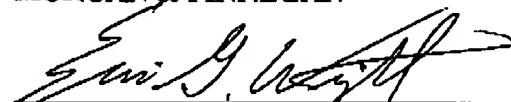
In view of the above, Applicants respectfully request that all rejections under 35 U.S.C. § 112 be withdrawn. Applicants assert that the above-identified application is in condition for allowance and request such action at this time.

### AUTHORIZATIONS

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deport Account No. 13-4503, Order No. 2324-7028US1. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,  
MORGAN & FINNEGAN

By:



Eric G. Wright  
Registration No. 48,045  
(202) 857-7887 Telephone  
(202) 857-7929 Facsimile

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Mailing Address:  
MORGAN & FINNEGAN  
3 World Financial  
New York, New York 10281-2101  
(212) 415-8700 Telephone  
(212) 415-8701 Facsimile

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As such, Applicants respectfully assert that claim 85 is definite. Further, applicants respectfully assert that dependent claim 86 is also definite.

In view of the above, Applicants request the withdrawal of the rejection of claims 85 and 86 under 35 U.S.C. § 112, ¶ 2. Further, Applicants respectfully assert that each of pending claims 34, 37, 38, 46-71 and 80-86 are definite and request the removal of all rejections and objections under 35 U.S.C. § 112, ¶ 2.

### CONCLUSION

In view of the above, Applicants respectfully request that all rejections under 35 U.S.C. § 112 be withdrawn. Applicants assert that the above-identified application is in condition for allowance and request such action at this time.

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Eric G. Wright  
Registration No. 48,045  
(202) 857-7887 Telephone  
(202) 857-7929 Facsimile

**Mailing Address:**  
MORGAN & FINNEGAN  
3 World Financial  
New York, New York 10281-2101  
(212) 415-8700 Telephone  
(212) 415-8701 Facsimile